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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/375,609	08/17/99	RHEINS	L 09373/002001

020985 HM12/1016  
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EXAMINER

PRASAD, S

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 10/16/00

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/375,609

Applicant(s)

RHEINS ET AL.

Examiner

Sarada C Prasad

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-63 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s).

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## DETAILED ACTION

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

**Group I.** Claims 1-10 are drawn to a method of obtaining a biological factor from cells below the stratum corneum of the skin of a subject, classified in class 530, subclass 412.

**Group II.** Claims 11-27 are drawn to a method of distinguishing ICD from ACD in a subject by quantifying a polynucleotide level encoding a cytokine, classified in class 435, subclass 6.

**Group III.** Claims 28-34 are drawn to a method of diagnosing ICD in a subject by quantifying the levels of a cytokine namely IL-4 and IL-8, in cells isolated from a subject, classified in class 435 and subclass 6.

**Group IV.** Claims 35-41 are drawn to a method of diagnosing ACD in a subject by quantifying the levels a polynucleotide encoding IL-4 in cells of a subject, classified in class 435 and subclass 6.

**Group V.** Claims 54-60 are drawn to a method of diagnosing ACD in a subject by quantifying a polynucleotide encoding IL-13 in cells of a subject, classified in class 435 and subclass 6.

**Group VI.** Claims 61-63 are drawn to kits comprising of a cell collection device, reagents for preserving polynucleotides, and mRNA detection reagents, classified in class 435 and subclass 6.

**Group VII.** Claims 42-53 are drawn to a method of identifying a compound which causes a dermatitis upon contact with skin by detecting a polynucleotide encoding a cytokine, classified in class 435 and subclass 7.1.

These inventions are patentably distinct for the following reasons:

The inventions in groups I-V are independent and distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case, use of invention I for a method of obtaining a biological factor from cells below the stratum corneum of the skin of a subject can be extended to diagnostic purposes other than determining the nature of dermatitis. Furthermore, the inventions II-V rely on different reagents for each of the said cytokines, namely IL-4, IL-8, and IL-13; and the expected end result in each case is not necessarily the same.

The instant kit described in invention VI is independent and distinct because its use in cell collection, preservation of polynucleotides and mRNA detection is not unique to determination of levels of cytokines.

The invention VII describing the method for identification of compounds that cause dermatitis is distinct and unrelated to each of the inventions I-VI, wherein practice of invention VII does not require practice of others, nor vice versa.

These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter.

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Subsequently different literature searches would be required proving a burden for the examiner. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected inventions, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.  
Examiner  
Art Unit 1646  
October 5, 2000

*Prema Mertz*  
PREMA MERTZ  
PRIMARY EXAMINER